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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/768,629

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EXAMINER

WACHTEL, EMILY L

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,629	Applicant(s) WEAVER ET AL.	
	Examiner EMILY WACHTEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>January 3, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) in view of Ohringer (U.S. Patent 3,811,466).

With regards to claim 1, Moorehead et al. teaches a pressure activated slit for medical applications (Col. 2 line 10) comprising a housing having a lumen extending therethrough from a proximal end to a distal end (Fig. 2 element 42), a flow control membrane (Fig. 5 elements 120, 124) including a mounting portion at which the flow control membrane is coupled to the housing (Fig. 5 element 120, Col. 6 lines 1-5) and a lumen occluding portion having a slit (Fig. 5 element 124, 146) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Col. 2 lines 29-32) and wherein a thickness of the mounting portion is greater than a thickness of the lumen occluding portion (Fig. 5 elements 120, 124, Col. 7 lines 17-20 base members add thickness to mounting portion and not to the area encompassing the slit). Moorehead et al. does not teach the mounting portion to cover a minority of a surface area of the lumen occluding portion in which the slit is

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disposed. However, Ohringer teaches a slit diaphragm (Fig. 2 diaphragm 17) mounted between control plate 19 and flanges 13 and 15 and that by varying the diameters of the openings surrounding the slit 31 you can control the flow and that the length of the slit is generally equal to or greater than the diameter (Col. 2 lines 40-41 and 50-51). Further, in Fig. 2 mounting flange 13 covers a minority of the surface area of the slit diaphragm. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to increase the size of the slit in Moorehead et al. in order to control the flow, as taught by Ohringer, and thereby increase the diameter of the mounting portion to accommodate the slit in the device in Moorehead et al. thereby causing the mounting portion to cover a minority of the surface area.

With regards to claim 3, Moorehead et al. teaches a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 5 elements 90, 120, 124, Col. 6 lines 47-53). Additionally, the outer periphery of the membrane (Fig. 5 elements 120, 130) is contiguous with the housing (Fig. 5 element 90). Therefore, the housing is applying a compressive retentive force on the membrane, as the membrane is secured within the housing and not free to move.

With regard to claim 2, Moorehead et al. teaches a flow control membrane composed of a first membrane (Fig. 5 element 124), an annular base membrane (Fig. 5 element 120) wherein an area of the base membrane substantially corresponds to that of the mounting portion and wherein the slit extend through the first membrane (Fig. 5). Moorehead et al. does not specifically teach bonding the first membrane to the annular base membrane, further, with regards to claim 4, Moorehead et al. does not teach

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adhesive bonding between membranes. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to adhesively bond and annular base (120) to a diaphragm (124) as such is an art recognized effective way of securing membrane layers together so as to maintain them in a desired position.

2. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 1 above as applied to claims 1 and 2 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

Moorehead et al. differs from claims 5 and 6 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col.7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use membranes of a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to. Moorehead et al. differs from claim 7 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the

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membrane portions (Fig. 5 elements 122, 124) in Moorehead et al. as applied to claims 5 and 6. It directly follows that the thickness of the mounting portion will be between 1 and 6 times the thickness of the lumen occluding portion.

Response to Amendment

3. Applicant's amendments to the abstract and specification have overcome the informalities and the objection has been withdrawn.

Response to Arguments

4. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection as necessitated by applicant's amendment.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571)270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. W./

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767